

10/729,122

Sheet 1 of 1

DRM PTO-1449
(modified)

U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No. D-21341 PCO
Diva

Serial No.: n/a

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

Applicant: James A. Williams et al.

Filing Date: here with 12/5/2003

Group/Art Unit:

7 CFR § 1.98(b))

U.S. PATENT DOCUMENTS

Examiner Initials	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
1	5,080,895	1/14/92	Tokoro			

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

2	Cato et al. (1986) "Clostridium," in <i>Bergey's Manual® of Systematic Bacteriology</i> , 2:1141-1200, Sneath (ed.), Williams & Wilkins
3	Engelkirk et al. (1992) "Classification," in <i>Principles and Practice of Clinical Anaerobic Bacteriology</i> , pp. 22-23, Star Publishing Co., Belmont, CA
4	Stephen and Pietrowski (1986) "Toxins Which Traverse Membranes and Deregulate Cells," in <i>Bacterial Toxins</i> , 2d ed., pp. 66-67, American Society for Microbiology
5	Berkow and Fletcher (eds.) (1992) "Bacterial Diseases," in <i>Merck Manual of Diagnosis and Therapy</i> , 16th ed., pp. 116-126, Merck Research Laboratories, Rahway, N.J.
6	Sigmund and Fraser (eds.) (1979) "Clostridial Infections," in <i>Merck Veterinary Manual</i> , 5th ed., pp. 396-409, Merck & Co., Rahway, N.J.
7	Hatheway (1990) "Bacteriophages and plasmids and their roles in coding for botulin neurotoxins," <i>Clin. Microbiol. Rev.</i> 3:73-74
8	Amon (1986) "Infant Botulism: Anticipating the Second Decade," <i>J. Infect. Dis.</i> 154:201-206
9	Amon (1980) "Infant Botulism," <i>Ann. Rev. Med.</i> 31:541-559
10	MacDonald et al. (1986) "The Changing Epidemiology of Adult Botulism in the United States," <i>Am. J. Epidemiol.</i> 124:794-799
11	Tacket et al. (1984) "Equine Antitoxin Use and Other Factors That Predict Outcome in Type A Foodborne Botulism," <i>Am. J. Med.</i> 76:794-798
12	Swartz (1990) "Anaerobic Spore-Forming Bacilli: The Clostridia," in <i>B.D. Microbiology</i> , 4th edition, pp. 633-646, Davis et al (eds.), J.B. Lippincott Co.
13	Holzer (1962) "Botulismus durch Inhalation," <i>Med. Klin.</i> 41:1735-738
14	Franz et al. (1993) in <i>Botulinum and Tetanus Neurotoxins</i> , pp. 473-476, B.R. DasGupta, ed., Plenum Press, NY
15	Amon et al. (1981) "Infant Botulism: Epidemiology and Relation to Sudden Infant Death Syndrome," <i>Epidemiol. Rev.</i> 3:45-66
16	Frankovich and Amon (1991) "Clinical Trial of Botulism Immune Globulin for Infant Botulism," <i>West. J. Med.</i> 154:103
17	Sugiyama (1980) "Clostridium botulinum Neurotoxin," <i>Microbiol. Rev.</i> 44:419-448
18	Balady (1991) "Botulism Antitoxin Fielded for Operation Desert Storm," <i>USAMRDC Newsletter</i> , p. 6
19	Schwarz and Amon (1992) "Botulism Immune Globulin for Infant Botulism Arrives-One Year and A Gulf War Later," <i>Western J. Med.</i> 156:197-198
20	Peterson et al. (1979) "The Sudden Infant Death Syndrome and Infant Botulism," <i>Rev. Infect. Dis.</i> 1:630-634
21	Amon et al. (1978) "Intestinal Infection and Toxin Production by Clostridium Botulinum as One Cause of Sudden Infant Death Syndrome," <i>Lancet</i> , pp. 1273-1277
22	Informational Brochure for the Pentavalent (ABCDE) Botulinum Toxoid, Centers for Disease Control, Rev. 1995, pp. 1-3 and 3 unnumbered pages
23	Brooks et al. (eds.) (1991) "Infections Caused by Anaerobic Bacteria," in <i>Jawetz, Melnick & Adelberg's Medical Microbiology</i> , 19th ed., pp. 257-262, Appleton & Lange, San Mateo, CA
24	Engelkirk et al. (1992) <i>Principles and Practice of Clinical Anaerobic Bacteriology</i> , pp. 64-67, Star Publishing Co., Belmont, CA
25	Lyerly et al. (1992) "Characterization of a Toxin A-Negative, Toxin B-Positive Strain of Clostridium difficile," <i>Infect. Immun.</i> 60:4633-4639
26	Borriello et al. (1990) "Virulence Factors of Clostridium difficile," <i>Rev. Infect. Dis.</i> , 12(Suppl. 2):S185-S191
27	Lyerly et al. (1985) "Effects of Clostridium difficile Toxins Given Intragastrically to Animals," <i>Infect. Immun.</i> 47:349-352

Examiner:

Date Considered: 2/7/05

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: <u>D-292ACIPAT</u>	Serial No.: <u>N/A</u>
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)				Applicant: <u>James A. Williams et al.</u>	
				Filing Date: <u>here with</u>	Group Art Unit:
(37 CFR § 1.98(b))					
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)					
28	Rolfe (1990) "Binding Kinetics of <i>Clostridium difficile</i> Toxins A and B to Intestinal Brush Border Membrane: from Infant and Adult Hamsters," <i>Infect. Immun.</i> 59:1223-1230				
29	Kim and Rolfe (1987) "The Protective Role of Antibody to Toxin A in <i>Clostridium difficile</i> - Induced Ileocolitis," <i>Abstr. Ann. Meet. Am. Soc. Microbiol.</i> 69:62				
30	Banno et al. (1984) "Biochemical Characterization and Biologic Actions of Two Toxins (D-1 and D-2) From <i>Clostridium difficile</i> ," <i>Rev. Infect. Dis.</i> 6(Suppl. 1):S11-S20				
31	Rihn et al. (1984) "A New Purification Procedure for <i>Clostridium difficile</i> Enterotoxin," <i>Biochem. Biophys. Res. Comm.</i> 124:690-695				
32	Justus et al. (1982) "Myoelectric Effects of <i>Clostridium difficile</i> : Motility-Altering Factors Distinct From its Cytotoxin and Enterotoxin in Rabbits," <i>Gastroenterol.</i> 83:836-843				
33	Finegold et al. (1992) "Antimicrobial-Associated Pseudomembranous Colitis," in <i>Clinical Guide to Anaerobic Infections</i> , pp. 88-89, Star Publishing Co., Belmont, CA				
34	United States Pharmacopoeia (1990) United States Pharmacopoeial Convention, Vol. XXII:1515-1516 Rockville, MD				
35	FDA Guidelines for Parenteral Drugs (December 1987) <i>Le., Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices</i>				
36	Pearson (1985) "Equivalency of LAL and USP Rabbit Pyrogen Tests," in <i>Pyrogens: endotoxins, lal testing and depyrogenation</i> , Marcel Dekker, NY, pp. 150-155				
37	Minton (1995) "Molecular Genetics of Clostridial Neurotoxins," <i>Curr. Top. Microbiol. Immunol.</i> 195:161-194				
38	Benedict and Yamaga (1966) "Immunoglobulins and Antibody Production in Avian Species," in <i>Comparative Immunology</i> , pp. 335-375 (J.J. Marchaloni, ed.), Blackwell, Oxford				
39	Patterson et al. (1962) "Antibody Production and Transfer to Egg Yolk in Chickens," <i>Immunol.</i> 89:272-278				
40	Carroll and Stollar (1983) "Antibodies of Calf Thymus RNA Polymerase II from Egg Yolks of Immunized Hens," <i>J. Biol. Chem.</i> 258:24-26				
41	Polson et al. (1980) "Antibodies to Proteins from Yolk of Immunized Hens," <i>Immunol. Comm.</i> 9:495-514				
42	DasGupta and Sugiyama (1972) "A Common Subunit Structure In <i>Clostridium Botulinum</i> Type A, B, and E Toxins," <i>Biochem. Biophys. Res. Commun.</i> 48:108-112				
43	DasGupta (1990) "Structure and Biological Activity of Botulinum Neurotoxin," <i>J. Physiol.</i> 84:220-228				
44	Halpern and Loftus (1993) "Characterization of the Receptor-binding Domain of Tetanus Toxin," <i>J. Biol. Chem.</i> 268:11188-11192				
45	Whelan et al. (1992) "Molecular Cloning of the <i>Clostridium botulinum</i> Structural Gene Encoding the Type B Neurotoxin and Determination of Its Entire Nucleotide Sequence," <i>Appl. Environ. Microbiol.</i> 58:2345-2354				
46	Sakaguchi (1983) " <i>Clostridium Botulinum</i> Toxins," <i>Pharmac. Ther.</i> 19:165-194				
47	Moberg and H. Sugiyama (1978) "Affinity Chromatography Purification of Type A Botulinum Neurotoxin from Crystalline Toxic Complex," <i>Appl. Environ. Microbiol.</i> 35:878-880				
48	Thalley et al. (1993) "Development of an Avian Antitoxin to Type A Botulinum Neurotoxin," in <i>Botulinum and Tetanus Neurotoxins</i> , pp. 467-472, B.R. DasGupta, ed., Plenum Press, NY				
49	Schantz and Johnson (1992) "Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine," <i>Microbiol. Rev.</i> 56:80-99				
50	Makoff et al. (1989) "Expression of Tetanus Toxin Fragment C in <i>E. Coli</i> : Its Purification and Potential Use as a Vaccine," <i>Bio/Technology</i> 7:1043-1046				
51	Makoff et al. (1989) "Expression of tetanus toxin fragment C in <i>E. coli</i> : high level expression by removing rare codons," <i>Nucl. Acids Res.</i> 17:10191-10202				
Examiner: <u>[Signature]</u>		Date Considered: <u>8/17/08</u>			
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: D-24390-PON

Serial No.: n/a

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)Applicant: James A. Williams *et al.*Filing Date: *March 1991*

Group Art Unit:

(37 CFR § 1.98(b))

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

- 52 Halpern *et al.* (1990) "Cloning and Expression of Functional Fragment C of Tetanus Toxin," *Infect. Immun.* 58:1004-1009
- 53 Romanos *et al.* (1991) "Expression of tetanus toxin fragment C in yeast: gene synthesis is required to eliminate fortuitous polyadenylation sites in AT-rich DNA," *Nucleic Acids Res.* 19:1461-1467
- 54 Charles *et al.* (1991) "Synthesis of Tetanus Toxin Fragment C in Insect Cells by Use of a Baculovirus Expression System," *Infect. Immun.* 59:1627-1632
- 55 Popoff *et al.* (1991) "Characterization of the C3 Gene of *Clostridium botulinum* Types C and D and Its Expression in *Escherichia coli*," *Infect. Immun.* 59:3673-3679
- 56 LaPenotiere *et al.* (1993) "Development of a Molecular Engineered Vaccine for *C. Botulinum* Neurotoxins," in *Botulinum and Tetanus Neurotoxins*, B.R. DasGupta, ed., Plenum Press, NY, pp. 463-466
- 57 Thompson *et al.* (1990) "The complete amino acid sequence of the *Clostridium botulinum* type A neurotoxin, deduced by nucleotide sequence analysis of the encoding gene," *Eur. J. Biochem.* 189:73-81
- 58 LaPenotiere *et al.* (1995) "Expression of a Large, Nontoxic Fragment of Botulinum Neurotoxin Serotype A and Its Use as an Immunogen," *Toxicon*. 33:1383-1386
- 59 Middlebrook and Brown (1995) "Immunodiagnosis and Immunotherapy of Tetanus and Botulinum Neurotoxins," *Curr. Top. Microbiol. Immunol.* 195:89-122
- 60 Hutson *et al.* (1994) "Nucleotide Sequence of the Gene Coding for Non-Proteolytic *Clostridium botulinum* Type B Neurotoxin: Comparison with Other Clostridial Neurotoxins," *Curr. Microbiol.* 28:101-110
- 61 Poulet *et al.* (1992) "Sequences of the Botulinum Neurotoxin E Derived from *Clostridium Botulinum* Type E (Strain Beluga) and *Clostridium Butyricum* (Strains ATCC 43181 and ATCC 43755)," *Biochem. Biophys. Res. Commun.* 183:107-113
- 62 Whelan *et al.* (1992) "The complete amino acid sequence of the *Clostridium botulinum* type-E neurotoxin, derived by nucleotide-sequence analysis of the encoding gene," *Eur. J. Biochem.* 204:657-667
- 63 Fujii *et al.* (1993) "The complete nucleotide sequence of the gene encoding the nontoxic component of *Clostridium botulinum* type E progenitor toxin," *J. Gen. Microbiol.* 139:79-86
- 64 Delmee *et al.* (1990) "Characterization of Flagella of *Clostridium difficile* and Their Role in Serogrouping Reactions," *J. Clin. Microbiol.* 28:2210-2214
- 65 Delmee and Avesani (1990) "Virulence of ten serogroups of *Clostridium difficile* in hamsters," *J. Med Microbiol.* 33:85-90
- 66 Toma *et al.* (1988) "Serotyping of *Clostridium difficile*," *J. Clin. Microbiol.* 26:426-428
- 67 Delmee *et al.* (1985) "Serogrouping of *Clostridium difficile* Strains by Slide Agglutination," *J. Clin. Microbiol.* 21:323-327
- 68 Davies and Borriello (1990) "Detection of Capsule in Strains of *Clostridium difficile* of Varying Virulence and Toxicogenicity," *Microbial Path.* 9:141-146
- 69 Edelstein (1990) "Processing Clinical Specimens for Anaerobic Bacteria: Isolation and Identification Procedures," in *Bailey and Scott's Diagnostic Microbiology*, pp. 477-507, C.V. Mosby Co. Baron and Finegold (eds.)
- 70 Padhye *et al.* (1990) "Production and Characterization of a Monoclonal Antibody Specific for Enterohemorrhagic *Escherichia coli* of Serotypes O157:H7 and O26:H11," *J. Clin. Microbiol.* 29:99-103
- 71 Lyerly *et al.* (1991) "Passive Immunization of Hamsters Against Disease Caused by *Clostridium difficile* by Use of Bovine Immunoglobulin G Concentrate," *Infect. Immun.* 59:2215-2218
- 72 DasGupta & Sathyamoorthy (1984) "Purification and Amino Acid Composition of Type A Botulinum Neurotoxin," *Toxicon*, 22:415-424
- 73 Singh & DasGupta (1989) "Molecular Differences Between Type A Botulinum Neurotoxin and Its Toxoid," *Toxicon* 27:403-410

Examined:

Date Considered: *2/20/85*

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark OfficeAttorney Docket No.: 1-2439CIPCON Serial No.: n/aINFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)Applicant: James A. Williams et al

37 CFR § 1.98(b))

Filing Date: 12/20/94

Group Art Unit:

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

180	74	Towbin et al. (1979) "Electrophoretic Transfer of Proteins from Polyacrylamide Gels to Nitrocellulose Sheets: Procedure and Some Applications," <i>Proc. Natl. Acad. Sci. USA</i> , 76:4350-4354
	75	Weber and Osborn (1975) "Proteins and Sodium Dodecyl Sulfate: Molecular Weight Determination on Polyacrylamide Gels and Related Procedures," in <i>The Proteins</i> , pp. 179-223, 3d Edition (H. Neurath & R.L. Hill, eds), Academic Press, NY
	76	Carroll and Laughon (1987) "Production and purification of polyclonal antibodies to the foreign segment of β -galactosidase fusion proteins," in <i>DNA Cloning: A Practical Approach</i> , Vol.III, pp. 89-111, D. Glover (ed.) IRL Press, Oxford
	77	Thalley and Carroll (1990) "Rattlesnake and Scorpion Antivenoms From The Egg Yolks of Immunized Hens," <i>Bio/Technology</i> 8:934-938
	78	Ohishi et al. (1977) "Oral Toxicities of <i>Clostridium botulinum</i> Toxins in Response to Molecular Size," <i>Infect. Immun.</i> 16:106-107
	79	Wren et al. (1991) "Antigenic Cross-Reactivity and Functional Inhibition by Antibodies to <i>Clostridium difficile</i> Toxin A, <i>Streptococcus mutans</i> Glucan-Binding Protein, and a Synthetic Peptide," <i>Infect. Immun.</i> 59:3151-3155
	80	Ehrich et al. (1980) "Production of <i>Clostridium difficile</i> Antitoxin," <i>Infect. Immun.</i> 28:1041-1043
	81	McGee et al. (1992) "Local induction of tumor necrosis factor as a molecular mechanism of mucosal damage by gonococci," <i>Microb. Path.</i> 12:333-341
	82	Fekety (1986) "Animal Models of Antibiotic-Induced Colitis," in <i>Experimental Models in Antimicrobial Chemotherapy</i> , 2:61-72, Zak and Sande (eds.), Harcourt Brace Jovanovich, NY
	83	Borriello et al. (1987) " <i>Clostridium difficile</i> -a spectrum of virulence and analysis of putative virulence determinants in the hamster model of antibiotic-associated colitis," <i>J. Med. Microbiol.</i> 24:53-64
	84	Kim et al. (1987) "Immunization of Adult Hamsters Against <i>Clostridium difficile</i> -Associated Ileocolitis and Transfer of Protection to Infant Hamsters," <i>Infect. Immun.</i> 55:2984-2992
	85	Borriello et al. (1988) "Mucosal Association by <i>Clostridium difficile</i> in the hamster gastrointestinal tract," <i>J. Med. Microbiol.</i> 25:191-196
	86	Dove et al. (1990) "Molecular Characterization of the <i>Clostridium difficile</i> Toxin A Gene," <i>Infect. Immun.</i> 58:480-488
	87	Williams et al. (1995) "Expression of foreign proteins in <i>E. coli</i> using plasmid vectors and purification of specific polyclonal antibodies," in <i>DNA Cloning 2: Expression Systems</i> , pp. 15-58, Glover and Hames (eds.) IRL Press, Oxford
	88	von Eichel-Streiber and Sauerborn (1990) " <i>Clostridium difficile</i> Toxin A Carries a C-Terminal Repetitive Structure Homologous to the Carbohydrate Binding Region of Streptococcal Glycosyltransferases," <i>Gene</i> 96:107-113
	89	Wren and Tabaqchali (1987) "Restriction Endonuclease DNA Analysis of <i>Clostridium difficile</i> ," <i>J. Clin. Microbiol.</i> 25:2402-2404
	90	Price et al. (1987) "Cloning of the Carbohydrate-binding Portion of the Toxin A Gene of <i>Clostridium difficile</i> ," <i>Curr. Microbiol.</i> 16:55-60
	91	Krivan et al. (1986) "Cell Surface Binding Site for <i>Clostridium difficile</i> Enterotoxin: Evidence for a Glycoconjugate Containing the Sequence Gal α 1-3Gal β 1-4GlcNAc," <i>Infect. Immun.</i> 53:573-581
	92	von Eichel-Streiber et al. (1989) "Cloning and Characterization of Overlapping DNA Fragments of the Toxin A Gene of <i>Clostridium difficile</i> ," <i>J. Gen. Microbiol.</i> 135:55-64
	93	Lyery et al. (1989) "Nonspecific Binding of Mouse Monoclonal Antibodies to <i>Clostridium difficile</i> Toxins A and B," <i>Curr. Microbiol.</i> 19:303-306
	94	Lyery et al. (1990) "Vaccination Against Lethal <i>Clostridium difficile</i> Enterocolitis with a Nontoxic Recombinant Peptide of Toxin A," <i>Curr. Microbiol.</i> 21:29-32
	95	Swanson et al. (1991) "In Vitro and In Vivo Evaluation of Tiacumcins B and C Against <i>Clostridium difficile</i> ," <i>Antimicro. Agents and Chemo.</i> 35:1108-1111
	96	Swanson et al. (1989) "Phenelfamycins, a Novel Complex of Elmamycin-type Antibiotics, III. Activity In Vitro and in a Hamster Colitis Model," <i>J. Antibiotics</i> 42:94-101

Examiner:

Date Considered: 3/5/95

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark OfficeAttorney Docket No.: D-2133CIP/CONSerial No.: 211aINFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)Applicant: James A. Williams et al.Filing Date: November 14, 1992

Group Art Unit:

(37 CFR § 1.98(b))

97	von Eichel-Streiber <i>et al.</i> (1992) "Comparative Sequence Analysis of the <i>Clostridium difficile</i> Toxins A and B," Molec. Gen. Genetics 233:260-268
98	Barroso <i>et al.</i> (1990) "Nucleotide Sequence of <i>Clostridium difficile</i> Toxin B Gene," Nucl. Acids Res. 18:4004
99	Thompson <i>et al.</i> (1990) "The complete amino acid sequence of the <i>Clostridium botulinum</i> type A neurotoxin, deduced by nucleotide sequence analysis of the encoding gene," Eur. J. Biochem. 189:73-81
100	Riggs (1989) in <i>Current Protocols in Molecular Biology</i> , Vol. 2, Ausubel, <i>et al.</i> (Eds.) pp. 16.6.1-16.6.14
101	Schantz and Kautter (1978) "Microbiological Methods: Standardized Assay for <i>Clostridium botulinum</i> Toxins," J. AOAC 61:96-99
102	Investigational New Drug (BB-IND-3703) application by the Surgeon General of the Department of the Army to the Federal Food and Drug Administration
103	Pearson (1985) <i>Pyrogens: endotoxins, LAL testing and depyrogenation</i> , Marcel Dekker, NY, pp. 23-56
104	Smith and Corcoran (1994) "Expression and Purification of Glutathione-S-Transferase Fusion Proteins," Current Protocols in Molecular Biology, Supplement 28:16.7.1-16.7.7
105	Gragerov <i>et al.</i> (1992) "Cooperation of GroEL/GroES and DnaK/DnaJ heat shock proteins in preventing protein misfolding in <i>Escherichia coli</i> ," Proc. Natl. Acad. Sci. USA 89:10341-10344
106	Fujii <i>et al.</i> (1990) "The Nucleotide and Deduced Amino Acid Sequences of <i>EcoRI</i> Fragment Containing the 5'-Terminal Region of <i>Clostridium botulinum</i> Type E Toxin Gene Cloned from Mashike, Iwanai and Otaru Strains," Microbiol. Immunol. 34:1041-1047
107	Kimura <i>et al.</i> (1990) "The Complete Nucleotide Sequence of the Gene Coding for Botulinum Type C ₁ Toxin in the C-St Phage Genome," Biochem. Biophys. Res. Comm. 171:1304-1311
108	Sunagawa <i>et al.</i> (1992) "The Complete Amino Acid Sequence of the <i>Clostridium botulinum</i> Type D Neurotoxin, Deduced by Nucleotide Sequence Analysis of the Encoding Phage d-164 Genome," J. Vet. Med. Sci. 54:905-913
109	Binz <i>et al.</i> (1990) "Nucleotide sequence of the gene encoding <i>Clostridium botulinum</i> neurotoxin type D," Nucleic Acids Res. 18:5556
110	Campbell <i>et al.</i> (1993) "Nucleotide sequence of the gene coding for <i>Clostridium botulinum</i> (<i>Clostridium argentinense</i>) type O neurotoxin: genealogical comparison with other clostridial neurotoxins," Biochim. Biophys. Acta 1216:487-491
111	East <i>et al.</i> (1992) "Sequence of the gene encoding type F neurotoxin of <i>Clostridium botulinum</i> ," FEMS Micro. Letters 96:225-230
112	Niemann (1992) "Clostridial Neurotoxins - Proposal of a Common Nomenclature," Toxicon 30:223-225
113	Food and Drug Administration Document (Docket No. 79D-0465) 53 FR 5044, February 19, 1988
114	Food and Drug Administration Document (Docket No. 79D-0465) 48 FR 27835, June 17, 1983

Examiner: [Signature]Date Considered: 2/20/95

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Application Number: .. 212

Div 2

Group Art Unit:

164

**EXAMINER
INITIAL**

DOCUMENT NUMBER

DATE _____

Plotkin et al., Vaccines, published by W.B. Saunders Company, Philadelphia, p. 571 (1988)
Nygren, P.-A. Et al. Trends in Biotechnology 12(5): 184-188

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to the applicant.